



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. : 10/657,378 : Confirmation No. 9440
Applicant : Scott T. Latterell
Filed : September 8, 2003
TC/A.U. : 3739
Examiner : Rollins, Rosiland Stacie:

Our Docket No. : 20010463.CIP
Customer No. : 23595

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. §1.132

I, Douglas S. Wahnschaffe, declare as follows:

1. I am a named co-inventor on the above-captioned application for patent.
2. I have a degree in Mechanical Engineering from the University of Minnesota and over 15 years experience working on a variety of electrosurgical instruments. Attached as Exhibit A hereto is a copy of my Curriculum Vitae.
3. Based upon the foregoing education, training and experience, I am competent to read and understand the construction and mode of operation of the Wrublewski Patent 6,174,309 when being used to electrosurgically cut and coagulate (seal) various types of tissues encountered in open surgical procedures. I am also quite familiar with the use of the instrument described and claimed in the above-captioned application and how its contoured jaws interact with various tissue types.
4. In the jaw assembly used in the present invention, one jaw member carries a sealing electrode that has a recess running longitudinally along its length axis where the sidewalls of the recess make an oblique angle with respect to the width axis of the jaw assembly. The other jaw member carries a sealing electrode that has a shape that is complimentary to the shape of the recess in the first sealing electrode. Because of the claimed shapes of the first and second sealing electrodes, when the jaws are squeezed

closed on a layer of body tissue, the tissue becomes tensioned or taut, permitting the cutting electrode that is fixedly secured to one of the jaws to cut through the stretched tissue upon electrical energization of the cutting electrode.

5. I have studied the jaw profile in the Wrublewski '309 patent and based upon my experience, I can positively state that the jaws in the '309 patent do not impart any significant tension to the tissue. This mandates that the cutting electrode be spring biased, that is, movably biased against the tissue to be cut for any acceptable cutting to take place.

6. It is my further opinion, based on 15 years of directly applicable experience, that the absence of any obliquely shaped tensioning profile in the Wrublewski device precludes satisfactory electrosurgical cut if a stationary cutting electrode is employed. It is only because the Wrublewski device incorporates a movably biased cutting electrode that his device can function satisfactorily.

7. I have carefully considered the discussion at col. 4, lines 18-22 of the Wrublewski '309 patent that has been referred to by the Examiner to support the position that the Wrublewski jaws do serve to tension tissue. I am unable to agree with the Examiner's position. The above-referenced passage begins by saying that the tissue "remains clamped or held between the opposing jaws". It then goes on to say that this "immobilizes both free ends of the tissue as tension is released by cutting". The referenced passage does not state that the tissue is tensioned merely by the shape of the jaws. Instead, tension is imparted by the spring-biased, movable cutting element pressing against the tissue and this tension will be released once the tissue is severed. The passage, therefore, does not teach or suggest our pretensioning of the tissue by the use of a shaped jaw profile prior to the severing of the tissue by an electrosurgical cut from a stationary cutting member.

8. For the reasons presented above, it cannot properly be said that the shape configuration of the jaws and electrode surfaces is merely a matter of obvious design choice. It is the particular shape configuration that provides the functionality needed to provide the necessary tissue tension when an immovable cutting electrode is utilized.

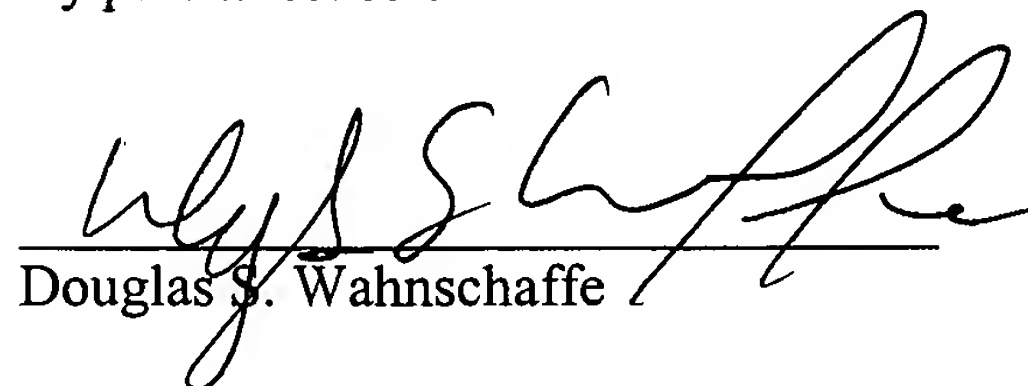
Serial No. 10/657,378

Declaration to Amendment Dated January 25, 2005

Reply to Office Action of November 17, 2004

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful and false statements may jeopardize the validity of this application or any patent issued thereon.

Dated: January 24th, 2005.


Douglas S. Wahnschaffe



Douglas Scott Wahnschaffe
13780 89th Circle NE, Otsego, MN 55330

Experience

Gyrus Medical/Everest Medical Minneapolis, MN

World leader in bipolar laparoscopic instruments.

Research and Development Manager

8/01-Present

- Developed electrosurgical system with multiple electrode instruments where one electrode has no direct connection to the generator output (patent pending)
- Developed and prototyped open bipolar forceps with electrical cutting.
- Developed and prototyped bipolar dissecting forceps with electrosurgical cutting in jaw center.
- Managed development of PK System Seal (open bipolar coagulating forceps). Performed testing to gain 510K sealing claim for vessel up to and including 7mm.
- Provide technical support to Guidant in development of 5th and 6th generation VASOVIEW® system

Development Engineer

5/97 – 8/01

- Developed and prototyped Wing™ Dissector (bipolar grasping dissector with electrosurgical cutting on outer perimeter for sweep cut).
- Developed bipolar electrosurgical hook probe for cutting and coagulating
- Developed connector to converted entire line of Everest branded bipolar products to Gyrus brand.
- Validated PlasmaKinetic generator outputs range of products.
- Designed QUADripolar™ Cutting Forceps (recognized as one of "New Products of the Year" at the Eighth International Meeting of Laparoendoscopic Surgeons). Design reduced lateral thermal tissue damage by
- Redesigned Bipolar Cutting Forceps to reduce labor by 50%, costs by 40% and field failures by 75%.
- Prototyped flexible bipolar scissors for Guidant's VASOVIEW® saphenous vein harvesting system.
- Developed flexible Bisector™ (bipolar ligating forceps) for Guidant's VASOVIEW® saphenous vein harvesting system.
- Redesigned BiSnare™ (bipolar polypectomy snare) to improve cutting performance and loop-shape retention.
- Prototyped 3mm laparoscopic scissors.

Manufacturing Engineer

10/96 – 5/97

- Evaluated returned product to identify source of failure and recommended improvements.
- Validate instruments to IEC 60601-2-2 and ANSI/AAMI HF 18-1993 Dielectric Standards.
- Revised product travelers and manufacturing processes to meet ISO standards.
- Performed and documented process validations

Production Manager/Supervisor

8/93 – 10/96

- Worked with outside services to provide temporary employees
- Supervised 4 leads and 35 production employees

Design Technician

6/89– 5/93

- Prototyped bipolar forceps-tipped scissors.
- Developed bonding method for laparoscopic bipolar scissors. Evaluated cutting blade edge design and materials.
- Evaluated methods for improving cut performance of bipolar sphincterotomy device by coating cut wire to increase impedance and reducing exposed cut wire to improve "fire off".
- Evaluated materials for use in BiLap™ Hook cutting and coagulating electrode.
- Developed recommended generator settings for bipolar coagulating forceps on common electrosurgical generators.
- Process development on bipolar polypectomy snare.
- Process development on GI bipolar coagulating probe

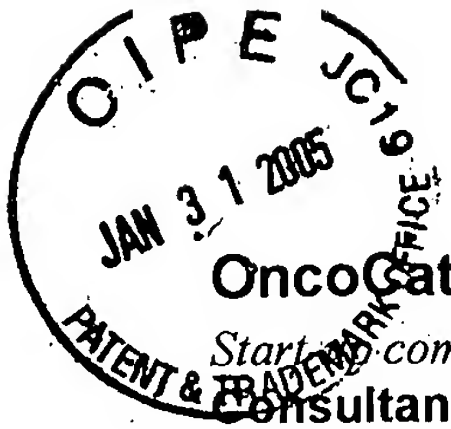
TFX Medical Plymouth, MN

OEM supplier of custom catheters, specializing in Teflon lined, braided and multi-duroameters.

Consultant

8/97 – 4/98

Process development of custom catheters



OncoGath

Plymouth, MN

10/95 – 2/97

Start-up company developing implantable silicone balloon for chemotherapy treatment of breast cancer.

Consultant

Performed design verifications testing

Completed initial build for clinical testing

Education

Bachelor of Science in Mechanical Engineering

University of Minnesota